Remarks

Claims 1-9, 11-22, and 25 are pending in this application. Claim 1 has been amended for the sole purpose of advancing prosecution.

Claim 1 has been amended to provide antecedent basis for "mouthpiece." The preamble of claim 1 now recites a "compliance monitor for a drug delivery device with a mouthpiece for administering a drug." Support for this amendment appears throughout the specification and claims as originally filed, for example, the fifth full paragraph on page 5, of the present specification.

Applicants, by cancelling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims cancelled herein or the original claim scope of any claim amended herein, in a continuing application.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, claims 1-9, 11-22 and 25 are rejected under 35 USC § 112, 2nd paragraph, as being indefinite.

The Examiner asserts that the phrase "the mouthpiece" has insufficient antecedent basis in the claim 1.

In view of the following, this rejection is respectfully traversed.

Applicants have amended claim to further recite "a mouthpiece." Claim 1 now recites a "compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from

the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth."

Accordingly, Applicants submit that the claims are not indefinite and that the phrase "the mouthpiece" has sufficient antecedent basis in claim 1. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. At pages 2-6 of the Official Action, claims 1-5, 7, 8, 12-22, and 25 have been rejected under 35 USC § 103(a) as being unpatentable over Wolf, et al. (US 5,809,997) in view of Olbrich et al. (US 6,733,464).

The Examiner newly asserts that Wolf teaches all the elements of claims 1-5, 7, 8, 12-22, and 25 except it does not disclose a sensor mounted so that the temperature sensor enters or contacts the user's mouth when a mouthpiece is placed in the mouth. However, the Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the compliance monitor of Wolf with the mounting of a temperature sensor as taught by Olbrich in order to provide the advantage of a fast response to user contact of device.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the

improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *See KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, neither Wolf nor Olbrich (1) teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*, (2) indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as

required by KSR, or (3) provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

The references do not teach or suggest every element of the claims

Claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; **a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**; a mouthpiece; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; **wherein the sensor is a temperature sensor for sensing body temperature** and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

The Examiner alleges that Wolf describes "a sensor (1560) for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose (column 19, lines 21-41.)" Page 3. Column 19, lines 21-41, recites:

> FIG. 17c also shows the air flow path starting from the air holes inlet 1440, through the air channel 1561 and through the main-PCB 1540 at the edge where the air flow sensor fast response thermistor 1560 is mounted. The air flow continues through the access hole 1260 in the wall of the actuator 1575 that the dynamic sensing arm 1555 is also extended through. It is important to understand that when the user is inhaling the medication by breathing in, ambient air would enter normally into the actuator 1575 around the sides of the vial/canister 1590, as is intended by the pharmaceutical manufacturer. Only a small fraction of ambient air enters through the accessory chronolog apparatus 1200, which allows the sensing of air flow. This channel of a fraction of the ambient air which enters the actuator 1575, has no interfering or altering effect of the medication being delivered out the mouthpiece 1585 of the commercially

> available vial/actuator combination 1220. The "states" of the air flow, as sensed by the fast response thermistor 1560 and the various tensions of force as they are applied to the strain gauge sensing area 1620 of the dynamic sensing arm 1555, shall be further discussed latter.

In contrast to the presently pending subject matter, Wolf's fast response thermistor, while measuring rapid changes in air temperature, is measuring temperature change only to determine direction of airflow and is not measuring body temperature (Col. 5, line 60, to col. 6, line 9). Wolf is measuring air temperature change only to determine direction of rapid changes in airflow and thereby detect and validate the proper inhalation sequence. Wolf describes their proper inhalation sequence as consisting of the user inhaling cool temperature air flowing in one direction, followed by exhaled air of warmer temperature flowing in the opposite direction from inhalation. Thereby, Wolf describes using air temperature to measure the sequence of inhaled air followed by exhaled air. **Wolf does not describe using "a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose" and wherein "the sensor is a temperature sensor for sensing body temperature" as recited in the claims.** Accordingly, Applicants submit that Wolf fails to teach or suggest all the elements of the presently pending subject matter

Olbrich does not remedy the deficiencies of Wolf. Olbrich describes the use of a temperature sensor for recording body temperature for diagnostic evaluation or recording ambient temperature. Col. 8, line 55, to col. 9, line 17. **Olbrich does not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**.

Applicants submit that the combination of references do not describe using a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose. **Importantly, Wolf describes the use of fast response thermistor to measure and validate the proper inhalation sequence. Wolf does not teach or suggest using the fast response thermistor to detect whether the device is "properly positioned". The Examiner is respectfully requested to expressly address this argument should this rejection be maintained.**

Accordingly, whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

The improvement suggested is not a predictable use of prior art elements according to their established functions

Further, the improvement suggested by the Examiner is not a predictable use of prior art elements according to their established functions as required in *KSR*. There is no teaching or suggestion in the combination of references to replace Wolf's fast response thermistor with the body temperature sensor of Olbrich. **One of ordinary skill in the art would not have predictably used the Olbrich body temperature sensor in place of Wolf's fast response thermistor because Olbrich's sensor would destroy the established function of Wolf's monitoring device. Olbrich's body temperature sensor would not meet the requirements of Wolf's rapid**

response thermistor to measure rapid changes in air temperature required to monitor and validate the proper inhalation sequence of Wolf's monitoring device.

Accordingly, whether taken alone, or in combination, the cited references do not indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*. In fact, replacing the rapid response thermistor of Wolf with the body temperature sensor of Olbrich would destroy the established function of Wolf's monitoring device. **The Examiner is respectfully requested to expressly address this argument should this rejection be maintained.**

No reasonable expectation of success

Further, the combination of references do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing. One of ordinary skill in the art reading the references would not have had a reasonable expectation of successfully using the Olbrich body temperature sensor in place of Wolf's fast response thermistor because Olbrich's sensor would destroy the established function of Wolf's monitoring device. **Olbrich's body temperature sensor would not have been reasonably expected to meet the requirements of Wolf's rapid response thermistor to measure rapid changes in air temperature required to monitor and validate the proper inhalation sequence of Wolf's monitoring device.**

Accordingly, whether taken alone, or in combination, the cited references do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing, as required by *KSR*. In fact, replacing the rapid

response thermistor of Wolf with the body temperature sensor of Olbrich would destroy the established function of Wolf's monitoring device. **The Examiner is respectfully requested to expressly address this argument should this rejection be maintained.**

In view of the foregoing, it is submitted that, whether taken alone or in combination, Wolf and Olbrich do not render the presently pending claims obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. At pages 6 and 7 of the Official Action, claims 6 and 9 have been rejected under 35 USC § 103(a) as being unpatentable over Wolf in view of Olbrich and further in view of Reinhold et al. (US Patent No. 7,073,499).

The Examiner asserts that it would have been obvious to provide the combination of Wolf and Olbrich with a drug delivery device of Reinhold, in the form of an inhaler, for topical administration of the drug. Further, the Examiner asserts that it would have been obvious to modify the combination with Reinhold in order to provide the advantage of allowing the invention to be used by patients with a wider range of medication needs.

In view of the following, this rejection is respectfully traversed.

A brief outline of relevant authority is set forth above.

As discussed, independent claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body

for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Amended claim 6 is directed to the compliance monitor according to claim 1, wherein the drug delivery device is for topical administration of the drug.

Amended claim 9 is directed to the compliance monitor according to claim 1, wherein the drug delivery device is selected from the group consisting of a dry powder inhaler, a pressurized metered dose inhaler and a nebuliser.

The combination of Wolf and Olbrich is discussed in detail above. The full discussion of Wolf and Olbrich is incorporated herein by reference.

Reinhold does not remedy the deficiencies of Wolf. Reinhold merely describes generally that a respiratory delivery system, for example, an inhaler, could be used for topical or nasal delivery of gaseous substances. *See* Reinhold at column 14, lines 58-63. Further, Reinhold describes that respiratory delivery systems can be either metered dose inhalers, dry powder inhalers or nebulizers. *See* Reinhold at column 1, lines 25-28. However, like Wolf and Olbrich, Reinhold fails to teach or suggest a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; **a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**; a mouthpiece; and a processor coupled to the switch and the sensor for recording whether or not the device was

properly positioned when the switch was actuated; **wherein the sensor is a temperature sensor for sensing body temperature** and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth, as recited in claim 1. Additionally, Applicants submit that Reinhold do not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed.

Accordingly, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, none of Wolf, Olbrich, and Reinhold teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In addition, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Reinhold do not indicate that the improvement suggested by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*.

Further, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Reinhold do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

In view of the foregoing, it is submitted that, whether taken alone or in combination, none of the cited references render the presently pending claims obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

IV. At page 7 of the Official Action, claim 11 has been rejected under 35 USC § 103(a) as being unpatentable over Wolf and Olbrich further in view of Trueba (US Patent No. 6,684,880).

The Examiner asserts that it would have been obvious to modify the combination of Wolf and Olbrich to include a light sensor as described in Trueba for sensing when the sensor is covered. Further, the Examiner asserts that it would have been obvious to modify the combination of Wolf and Olbrich to include the light sensor as described in Trueba in order to provide the advantage of p[providing a simple way of determining if the invention was properly used.

In view of the following, this rejection is respectfully traversed.

A brief outline of relevant authority is set forth above.

As discussed, independent claim 1 is directed to a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; wherein the sensor is a temperature sensor for sensing body temperature and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth.

Claim 11 is directed to the compliance monitor according claim 1, further comprising a light sensor for sensing when the sensor is covered.

The combination of Wolf and Olbrich is discussed in detail above. The full discussion of Wolf and Olbrich is incorporated herein by reference.

Trueba does not remedy the deficiencies of the combination of Wolf and Olbrich. Trueba merely describes the use of an optical sensor. *See* Trueba at column 13, lines 28-31. However, like Wolf and Olbrich, Trueba fails to teach or suggest a compliance monitor for a drug delivery device with a mouthpiece for administering a drug, comprising: a switch actuatable by a user on delivering a dose from the device; **a sensor for detecting whether the device is properly positioned in contact with or relative to the user's body for delivery of the dose**; a mouthpiece; and a processor coupled to the switch and the sensor for recording whether or not the device was properly positioned when the switch was actuated; **wherein the sensor is a temperature sensor for sensing body temperature** and the temperature sensor is mounted so that the temperature sensor enters or contacts the user's mouth when the mouthpiece is placed in the mouth, as recited in claim 1. Additionally, Applicants submit that Trueba does not teach or suggest a temperature sensor that directly determines body temperature, as presently claimed.

Accordingly, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, none of Wolf, Olbrich, and Trueba teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*.

In addition, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Trueba do not indicate that the improvement suggested

by the Examiner is a predictable use of prior art elements according to their established functions, as required by *KSR*.

Further, for the same reasons discussed above for the combination of Wolf and Olbrich, and incorporated herein by reference, whether taken alone, or in combination, Wolf, Olbrich, and Trueba do not provide a reasonable expectation that the proposed modification would have been successful at the time of filing.

In view of the foregoing, it is submitted that, whether taken alone or in combination, none of the cited references render the presently pending claims obvious within the meaning of 35 USC § 103(a). Accordingly, the Examiner is respectfully requested to withdraw this rejection.

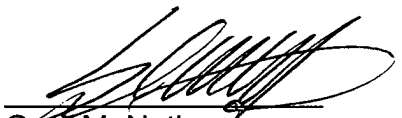
CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



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